

Adult CIRB - Early Phase Emphasis Meeting Agenda

April 18, 2023

I New Study - Initial Review

10579, Phase I trial of ZEN003694 (ZEN-3694) in combination with capecitabine in patients with solid tumors (Version Date 03/10/23)

II Amendment

10217, A Phase 1b Biomarker-Driven Combination Trial of Copanlisib, Olaparib, and Durvalumab (MEDI4736) in Patients with Advanced Solid Tumors (Version Date 01/20/23)

III Continuing Review

10486, Phase 2 Trial of the Combination of the BET inhibitor, ZEN003694 (ZEN-3694), and the PARP Inhibitor Talazoparib, in Patients with Molecularly-Selected Solid Tumors (ComBET) (Version Date 07/08/22)

IV Continuing Review

AMC-110, Risk-Adapted Therapy for HIV-Associated Anal Cancer (Version Date 10/19/21)

V Continuing Review

10404, A Phase 1 Trial of the ATR Inhibitor BAY 1895344 in Combination with Cisplatin and with Cisplatin Plus Gemcitabine in Advanced Solid Tumors with an Emphasis on Urothelial Carcinoma (Version Date 06/07/22)
